IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	
Plaintiff,	
v.	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC.,) O PUBLIC VERSION
Defendant.))
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA,	Confidential Version Filed: June 20, 2023
Defendant/Counter-Plaintiffs,	Public Version Filed: June 27, 2023
v.))
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.)))
Plaintiff/Counter-Defendants.)

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S OPPOSITION TO NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.'S MOTION FOR THE ISSUANCE OF A REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE

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June 20, 2023

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I. Introduction

Sarepta Therapeutics, Inc. ("Sarepta") and The University of Western Australia ("UWA") hereby oppose Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s (collectively, "NS") Motion for the Issuance of a Request for International Judicial Assistance asking the Court to issue the proposed Letter of Request to the Competent Authority of Australia to compel the testimony of two former UWA lab workers, Abbie Adams and Penny Meloni (the "Motion").

NS provides no justification for subjecting the parties to an unduly burdensome process merely to obtain cumulative and duplicative discovery. NS incorrectly portrays its Motion as necessary to get otherwise unobtainable information about the Wilton patents. What NS fails to mention, however, is that it has already obtained, or could have obtained, the information it seeks through party (or voluntarily appearing third-party) discovery through document requests and depositions. Indeed, every reason NS provides for seeking to go through the complicated and expensive Letter of Request process is tied to Dr. Stephen Wilton, whom NS recently deposed. During that deposition, NS either questioned or could have questioned Dr. Wilton about any topic in the letter of request that NS itself asserts is relevant to this litigation— NS's unwillingness to obtain this information from Dr. Wilton should not be an excuse to drag two non-parties from Australia into this litigation. Nor does NS reasonably explain the eleventh-hour decision to seek a Letter of Request despite its knowledge through publicly available information dating back to 2007. NS chose to wait until less than two months before the close of fact discovery to undertake the time-consuming Letter of Request process. NS's questionable timing is consistent with its shotgun approach to non-party discovery—burdening numerous non-party former Sarepta and UWA employees with subpoenas

seeking cumulative and duplicative material—which it timed to coincide with a busy deposition schedule. Whatever NS's motivations for its eleventh-hour Motion, allowing the Letter of Request to move forward would be prejudicial to Sarepta and UWA.

Because NS fails to justify its unduly burdensome and strategically-timed request for a Letter of Request, the Court should deny the Motion.

II. Background

The underlying litigation among NS, Sarepta, and UWA involves allegations of patent infringement by NS's product Viltepso® and Sarepta's product Vyondys 53®, with defenses of non-infringement and invalidity. Both products are antisense oligonucleotides (ASOs) approved in the United States for the treatment of Duchenne muscular dystrophy (DMD). Central to this dispute are NS's defenses to Sarepta's claim of infringement of patents owned by UWA and licensed by Sarepta (the "Wilton patents"). NS has also asserted seven patents in this action, which are referred to as the "NS patents." ¹

A. The Wilton Patents

The Wilton patents are the result of years of research, beginning prior to 2004, conducted in Dr. Wilton's research group by Drs. Wilton, Fletcher, and McClorey who were, at the time, employed by UWA. In collaboration, these scientists pioneered the use of ASOs to overcome certain dystrophin gene defects causing DMD, launching research in this area by many others. Dr. Wilton's research group employed several other workers, including

These other employees worked on various projects for the larger research group at the direction of Drs. Wilton, Fletcher, and/or McClorey as it related to their research.

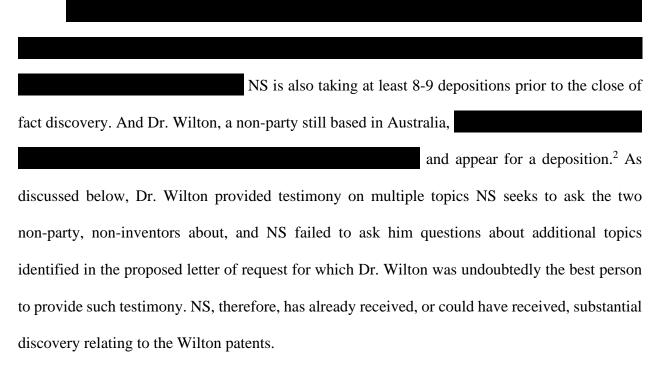
¹ UWA is an Australian research university that joined this case to address any perceived standing deficiency in connection with Sarepta's infringement counterclaims. UWA's discovery obligations should be proportional with that limited involvement in the case.

Through the dedicated research of Drs. Wilton, Fletcher, and McClorey, a non-provisional patent application was filed on June 28, 2005, which opened the door for decades of research and innovation in the area of ASOs for treatment of DMD. Drs. Wilton and Fletcher continued their research in this area at UWA for nearly another decade. Similarly, continued their employment in the lab and worked at the direction of Drs. Wilton and Fletcher and, in some instances, contributed to later innovations.

Ultimately, all the researchers left UWA to continue pursuing similar lines of research elsewhere. In 2006, when he received his PhD, Dr. McClorey left UWA to become a post-doctoral research scientist at the University of Oxford. And about 10 years ago, in 2013, Drs. Wilton and Fletcher moved from UWA to Murdoch University in Perth, Australia, where they continued their research in the same area. As part of this move, joined Drs. Wilton and Fletcher, and moved into life sciences sales.

B. The Ongoing Litigation and this Motion

The litigation between the parties has been pending for nearly two years. Pursuant to the case schedule, substantial completion of document production was to have occurred in January 2023 and the close of fact discovery is set for July 27, 2023.



None of the named inventors on the Wilton patents are still employed by UWA. Dr. McClorey left UWA in 2006 and Drs. Wilton and Fletcher left UWA in 2013. Dr. Wilton voluntarily agreed to produce documents

as well as fly to the United States from Perth, Australia, for a deposition that occurred last week. Moreover, despite being a non-party, Dr. Wilton agreed to be designated as a 30(b)(6) witness on behalf of both Sarepta and UWA on multiple topics relating to the Wilton patents,

As the head of the lab conducting the research that led to the Wilton patents, Dr. Wilton is the most knowledgeable individual who could have provided, and did provide, deposition testimony on the Wilton patents,

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² NS complains that Sarepta and UWA have only made Dr. Wilton, and not the other named inventors, available for a deposition. D.I. 215 at 5 n.2. As NS is aware, none of the named inventors are employed by either Sarepta or UWA, thus neither party can "agree[] to make" those inventors available for a deposition. This issue (and Sarepta's motion to compel NS to produce Dr. Takeda, an inventor on the NS patents, for deposition) is the subject of a pending discovery dispute among the parties. D.I. 226.

Despite the extensive document discovery that Sarepta, UWA, and Dr. Wilton have produced, the numerous depositions currently taking place, and time the parties have had for discovery, NS now, less than two months from the close of fact discovery, takes an expansive, shotgun approach to third-party discovery. D.I. 208, 211, 215.³ NS's third-party discovery it now seeks from these two third-party foreign nationals who were workers in Dr. Wilton's lab is unduly burdensome, not proportional to the needs of the case, and cumulative of discovery NS could have obtained through other means.

III. Legal Standard

For a motion to issue a Letter of Request, the "party seeking application of the Hague Convention proce[dures] bears the burden of persuading the Court of its necessity." *Purdue Pharma Prods. L.P. v. Par Pharms., Inc.*, C.A. No. 07–255–JJF, 2008 WL 3926158, at *1 (D. Del. Aug. 26, 2008); *see also Ingenico Inc. v. Ioengine, LLC*, C.A. No. 18-826-WCB, 2021 WL 765757, at *1 (D. Del. Feb. 26, 2021) (same). In evaluating the necessity for a Letter of Request, "a court must limit the frequency and extent of discovery that can be obtained from sources less burdensome or less expensive, or if it determines that the burden or expense of the proposed discovery outweighs its likely benefit." *Purdue*, 2008 WL 3926158 at *2 (citing Fed. R. Civ. 26(b)). Keeping in mind "the system's cumbersome nature," courts will deny motions "where the relevancy or materiality of the testimony sought is doubtful." *Route1 Inc. v. AirWatch LLC*, C.A. No. 17-0331-RGA, 2018 WL 6427145, at *1 (D. Del. Dec. 7, 2018). And while the Third Circuit has explained that a district court must provide some reason for denying a motion for Letter of

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³ On the eve of commencing a period wherein the parties are scheduled to take approximately 20 depositions, NS noticed its intent to depose and seek documents from, in addition to the non-parties who are the subject of this motion, Sarepta's contract manufacturer, and Sarepta's former employees Diane Frank, Richard Bestwick, Peter Sazani and Ryzsard Kole.

Request, it nonetheless "decline[d] to hold that a trial court must expressly set forth a 'good reason' for den[ial]." *Complaint of Bankers Trust Co.*, 752 F.2d 874, 890 (3rd Cir. 1984).

Because Letters of Request are a "complicated, dilatory and expensive system," courts apply a five-factor test "relevant to any comity analysis." *Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Court for Southern Dist. of Iowa*, 482 U.S. 522, 531, 544 n.28 (1987). The five factors are:

- (1) the importance to the ... litigation of the documents or other information requested;
- (2) the degree of specificity of the request;
- (3) whether the information originated in the United States;
- (4) the availability of alternative means of securing the information; and
- (5) the extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located.

Id.

A proper application of the "five-factor test requires a particularized analysis of the facts of a case, the sovereign interests involved, and the likelihood that resorting to the Hague Convention will prove effective." *Ingenico, LLC*, 2021 WL 765757 at *1; *see also Fraunhofer-Gesellschaft Zur Forderung der angewandten Forschung e.V. v. Sirus XM Radio Inc.*, C.A. No. 17-184-JFB-SRF, 2021 WL 861493, at *2 (D. Del. Mar. 8, 2021) ("Accordingly, the Supreme Court has directed federal courts to employ a case-by-case analysis to determine whether the use of the Hague Convention is the appropriate tool for obtaining evidence in a given proceeding.").

IV. Argument

As an initial matter, NS incorrectly relies on the "good cause" standard the Third Circuit expressly declined to adopt. *Compare* Motion at 4 ("Letters of request should be issued unless the

Court finds good cause to justify denial.") with Complaint of Bankers Trust Co., 752 F.2d at 890 ("[W]e decline to hold that a trial court must expressly set forth a 'good reason' for denying an application."). Even with the "good cause" standard applied, however, NS's Motion should be denied. To start, NS's Motion fails to provide an analysis of the Aerospatiale factors, or much of an analysis at all. See generally D.I. 215.⁴ Without any meaningful substantive analysis, NS fails to meet its "burden of persuading the Court of [the Letter of Request's] necessity." Purdue, 2008 WL 3926158 at *1. This alone warrants denial of NS's Motion. Id. Regardless, as shown below, an analysis of the five Aerospatiale factors only further demonstrates the futility of NS's attempt to seek this untimely discovery in Australia. As such, the Court should deny the Motion.

A. The Information Sought Is Not Important to the Litigation

The information sought by NS—numerous, irrelevant, and broad categories of deposition testimony from two former UWA lab technicians (D.I. 215-1, Ex. A at 8-10)—is of little-to-no importance to the ongoing litigation. The stated purpose of the Letter of Request relates to, allegedly,

D.I. 215 at 2-3, D.I. 215-1, Ex. A at 5-6. More specifically,

D.I. 215 at 5.

⁴ Having failed to address the elements of the relevant standard in its motion, fairness dictates that NS should be precluded from belatedly attempting to address them in its reply, to which Sarepta and UWA do not get a response. *See* D. Del. LR 7.1.3(c)(2) ("The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.").

indication that deposition topics are not directed to the specific subject matter or timeframe relevant to the Wilton patents, the Court should deny the Motion. *Route1*, 2018 WL 6427145 at *1 ("[W]here the relevancy or materiality of the testimony sought is doubtful, the court should not grant the application.") (quotations and citations omitted). Because the testimony NS seeks is neither relevant nor material, the Motion should be denied.

Neither proposed witness is an inventor of the Wilton patents. As NS correctly notes, were both authors of non-patent publications and inventors on UWA patent applications years after the effective filing date of the Wilton patents in suit. *See* D.I. 215-1 at 6-7 (listing four non-patent publications from 2007 and 2009) and 10 (including deposition topics asking about non-patent publications and an unrelated, 2010 patent publication, PCT/AU2010/001520). But being involved in later, unrelated publications as an author and inventor does not give NS free rein to seek testimony from

are not inventors. *See Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 12–3289 (PGS), 2013 WL 12203112, at *3 (D.N.J. June 7, 2013) ("In this matter, the [foreign-based] witnesses are neither being offered as experts…nor are they listed inventors of the '336 Patent which is the only patent currently at issue. The [foreign-based] witnesses are, instead, the inventors of [unrelated patents].").

The length of time between the publications NS relies on and the priority date of the Wilton

patents further highlights the tenuous connections NS seeks to make. Three of the papers NS cites are from 2007, years after the Wilton patents' effective filing date. D.I. 215-1 at 6. The remaining paper NS cites, along with the unrelated International Application No. PCT/AU/2010/001520, were published in 2009 or later. *Id.* at 6-7. These later publications simply have no bearing on See, e.g., id. ("Thus, the [foreign-based] witnesses" testimony regarding prior art at the time of the filing of the '336 patent is neither relevant nor is it likely to lead to the discovery of admissible evidence such that the Court will permit Defendants to proceed under the Hague Convention."). And to the extent NS argues that testimony on the unrelated publications "may lead to information concerning evidence that these witnesses actually which may impact the validity had a role in discovery of the patent-in-suit under 35 U.S.C. § 102(f)," this is based on speculation and is thus a "fishing expedition" that the Court should not permit. *Id.* at *4 (internal quotations omitted).

NS cannot justify this request for irrelevant and burdensome discovery.

NS provides only conclusory statements to support its claims of relevance. D.I. 215 at 4-6; 215-1. For example, NS vaguely asserts the information it hopes to discover relates to "issues directly relevant to the parties' disputes and material to NS's claims and defenses" and that the "importance...is supported and demonstrated D.I. 215 at 5. But performing experiments at the direction of an inventor does not make one an inventor. See Application of Herschler, 591 F.2d 693, 699 (C.C.P.A. 1979) (holding that an alleged joint inventor acted only under the other joint inventor's direction and thus was not an inventor). Nor does being a co-author on a paper with an inventor make on an inventor. See In re Katz, 687 F.2d 450, 455 (C.C.P.A. 1982) (holding that students who were working under the direction and control of the inventor were not proven to be joint inventors merely because they were listed as co-authors on an academic article describing the invention). These conclusory statements are not even close to sufficient enough to demonstrate relevance to warrant burdensome and costly foreign discovery. *Ingenico*, *LLC*, 2021 WL 765757 at *3 (finding factor one weighed in favor of denial when the moving party made only "conclusory assertions" regarding alleged involvement by foreign nationals in the reduction to practice of the patents-atissue). NS's pure speculation "is so speculative that the entire

endeavor to [obtain testimony] amounts to an international fishing expedition."⁵ *Route1*, 2018 WL 6427145 at *1.

Finally, the importance of the information to the litigation, or lack thereof, can be viewed through the lens of NS's discovery strategy. By its own admission, NS knew of Ms. Adams' and Ms. Meloni's roles in Dr. Wilton's laboratory since at least January of this year, nearly five months ago. *See* D.I. 215 at 3. And the publications NS relies on have been available online since before this litigation began. *See* D.I. 215-1 at 6-7 (citing documents from 2007 and 2009). NS's delays in requesting this foreign discovery highlights its own view of this information as unimportant and weighs against issuance. *See Merck*, 2013 WL 12203112 at *4 ("Applied here, the Court notes that Defendants filed this request in late April 2013, with less than two months left before the close of discovery on June 28, 2013.").

B. The Degree of Specificity of the Deposition Topics Is Lacking

The breadth of subject matter covered by the proposed deposition topics includes essentially all the possible work were a part of or even knew about during their time at UWA. D.I. 215-1, Ex. A at 8-10. Contrary to NS's assertion, the topics are not "narrowly tailored to...a specified time frame or on specified subject matter." D.I. 215 at 6. As discussed above, many requests are either unbounded in time and subject matter or cover unnecessarily broad time periods

D.I. 215-1 at 8-10. NS provides no explanation as to how its broad deposition topics—

unrelated publications

produced documents.

⁵ Importantly, NS's counsel had an opportunity to ask Dr. Wilton
but NS never asked.
Instead, NS's counsel asked only about information readily available from

from years after the Wilton patents' effective filing date, or essentially any work that could possibly be conducted in Dr. Wilton's lab—are related

D.I. 215 at 5.

Because NS fails to provide any justification for such "sweeping" testimony, the Motion "fails the second factor in *Aerospatiale*'s five-factor test." *Ingenico*, *LLC*, 2021 WL 765757 at *4.

C. The Information Sought Did Not Originate in the United States

The information NS Pharma seeks did not originate in the United States. NS Pharma's Motion concedes as much. See, e.g., D.I. 215 at 3, 4-5

D.I. 215-1, Ex. A at 9-10

NS does not even attempt to explain how the overwhelming majority of the information it seeks originated in or is located in anywhere except Australia. Factor three therefore weighs in favor of denial. Ingenico, LLC, 2021 WL 765757 at *3; Dyson, Inc. v. SharkNinja Operating LLC, No. 1:14-cv-0779, 2016
WL 5720702, at *3 (N.D. Ill. Sept. 30, 2016) ("Finally, the information did not originate in the

D. NS Has Ignored Alternative Means of Securing the Information

United States, and this factor weighs against issuing the Letters Rogatory.").

Any relevant, non-privileged information NS is seeking from these two non-inventors and non-parties in Australia has been, or could have been, obtained through discovery in the United States. NS admits it has already received relevant documents from Sarepta and non-party inventor Dr. Wilton. D.I. 215 at 5. Sarepta gathered and made available to NS

Moreover, Dr.

Wilton flew to the United States and was deposed by NS, despite being a non-party and despite NS refusing to make two of the NS patents named inventors available for deposition. Having all this information, NS nonetheless speculates, without support, that there must be more unique information

D.I. 215 at 4-6. NS's speculation does not warrant burdensome eleventh-hour foreign discovery of non-parties, when the discovery can be obtained from a party. *Route1*, 2018 WL 6427145 at *1 ("Defendant does little to address why Plaintiff is not a sufficient source of the documents Plaintiff allegedly provided to Fiera and De Jong."); *Purdue*, 2008 WL 3926158 at *2 ("Similarly, the Court concludes that the remaining topics of examination...are insufficiently relevant to the present action to justify the burden and expense they would impose, especially in light of the fact that *much of the information sought has already been produced or is publicly available*.") (emphasis added).

documents regarding the Wilton patents in its possession, all the information it seeks through the two non-inventors was or could have been obtained through Dr. Wilton, the named inventor whom NS recently deposed.

D.I. 215 at 2-3. Dr. Wilton is an inventor of the Wilton patents. *Id.* Dr. Wilton is an author on all four of the unrelated articles NS cites. D.I. 215-1, Ex. A at 6-7. And Dr. Wilton is an inventor listed on the unrelated patent application, PCT/AU2010/001520, NS cites. *Id.* at 10. Any testimony NS could hope to obtain from would be duplicative of testimony it already obtained, or could have obtained, from Dr. Wilton. *See Merck*, 2013 WL 12203112 at *4 ("Defendants have already noticed or taken depositions of the four inventors of the patent-in-suit who were also named inventors on the '147 and WO '679 patents.").

Even if, for the sake of argument, NS did not already have the relevant and non-privileged

And to the extent NS argues it requires information on
NS has not explained why it did not and could not
have obtained such information from Dr. Wilton or how such information would be different than
what Dr. Wilton could have provided. Route1, 2018 WL 6427145 at *1 ("Moreover, there is no
reason to believe that, assuming Fiera and De Jong do possess such information, the information
is different than what Plaintiff can produce.").
To be clear, this is not a situation where NS sought testimony from Dr. Wilton and could
not obtain it. Rather, NS obtained relevant testimony on multiple topics in its proposed letter of
request.
Information on other topics is readily available in documents already
produced,
Ex. 2.
And even though the proposed topics relating to the 2007, 2009, and 2010 publications are
irrelevant (see supra, § IV.A), Dr. Wilton is an author on every cited publication (D.I. 215-1 at
6-7, 10) and could have answered questions regarding these publications.

NS filed its Motion, including the letter of request containing its proposed topics, *after* Dr. Wilton agreed to fly from Australia to the United States for a deposition but *before* the deposition

occurred. That is, before it had even deposed Dr. Wilton, NS asserted that it could not obtain the information it sought from any source outside of Having been given the opportunity to obtain the information it seeks, NS has no justification to further pursue this Motion. *See, e.g., Route1*, 2018 WL 6427145 at *1; *Purdue*, 2008 WL 3926158 at *2; *Merck*, 2013 WL 12203112 at *4.

Because NS has failed to show it cannot obtain the information it seeks from party and voluntary discovery in the United States, factor four weighs in favor of denial.

E. Whether Compliance Undermines Australian Law or Noncompliance Would Undermine American Law Is Neutral

The issues of comity here weigh in favor of neither party. NS provides no explanation as to whether compliance would undermine Australian law or whether noncompliance would undermine American law. *See generally* D.I. 215. At best, due to NS's lack of explanation, this factor is neutral.

Accordingly, four of the five *Aerospatiale* factors weigh in favor of denial and the final factor is neutral. Because NS has failed to justify its burdensome, duplicative, and untimely request for discovery, its request should be denied.

V. Conclusion

For all the reasons discussed above, the Court should deny NS's Motion for the Issuance of a Request for International Judicial Assistance asking the Court to issue the proposed Letter of Request to the Competent Authority of Australia.

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CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 20, 2023, upon the following in the manner indicated:

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